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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,088	11/13/2001	Michael Dyson	B45172	9241
20462	7590	08/26/2003		
SMITHKLINE BEECHAM CORPORATION CORPORATE INTELLECTUAL PROPERTY-US, UW2270 P. O. BOX 1539 KING OF PRUSSIA, PA 19406-0939			EXAMINER HUYNH, PHUONG N	
			ART UNIT 1644	PAPER NUMBER 7
DATE MAILED: 08/26/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/914,088	<b>Applicant(s)</b> DYSON ET AL.
	<b>Examiner</b> " Neon" Phuong Huynh	<b>Art Unit</b> 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 13 November 2001.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 42-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 42-83 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |                                                                                                |                                                                             |
|------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____                                    |

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### **DETAILED ACTION**

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
2. Claims 42-83 are pending.

#### ***Election/Restrictions***

3. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:  
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

- I. Claims 42-43, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P1 of SEQ ID NO: 1**.
2. Claims 42, 44, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P2 of SEQ ID NO: 2**.
3. Claims 42, 45, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P3 of SEQ ID NO: 3**.
4. Claims 42, 46, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P4 of SEQ ID NO: 4**.
5. Claims 42, 47, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P5 of SEQ ID NO: 5**.

6. Claims 42, 48, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P6 of SEQ ID NO: 6**.
7. Claims 42, 49, 51-52, and 58-67 drawn to a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and a peptide wherein the surface exposed epitope Cε2 is **P7 of SEQ ID NO: 7**.
8. Claims 42-43, drawn to a **non-peptide mimotope of P1 of SEQ ID NO: 1**.
9. Claims 42, and 44, drawn to a **non-peptide mimotope of P2 of SEQ ID NO: 2**.
10. Claims 42 and 45, drawn to a **non-peptide mimotope of P3 of SEQ ID NO: 3**.
11. Claims 42, and 46, drawn to a **non-peptide mimotope of P4 of SEQ ID NO: 4**.
12. Claims 42, and 47, drawn to a **non-peptide mimotope of P5 of SEQ ID NO: 5**.
13. Claims 42, and 48, drawn to a **non-peptide mimotope of P6 of SEQ ID NO: 6**.
14. Claims 42, and 49, drawn to a **non-peptide mimotope of P7 of SEQ ID NO: 7**.
15. Claims 42-43, 50, and 58-67, drawn to a **peptide mimotope of P1 of SEQ ID NO: 1**.
16. Claims 42, 44, 50, and 58-67, drawn to a **peptide mimotope of P2 of SEQ ID NO: 2**.
17. Claims 42, 45, 50, and 58-67, drawn to a **peptide mimotope of P3 of SEQ ID NO: 3**.
18. Claims 42, 46, 50, and 58-67, drawn to a **peptide mimotope of P4 of SEQ ID NO: 4**.
19. Claims 42, 47, 50, and 58-67, drawn to a **peptide mimotope of P5 of SEQ ID NO: 5**.
20. Claims 42, 48, 50, and 58-67, drawn to a **peptide mimotope of P6 of SEQ ID NO: 6**.
21. Claims 42, 49, 50, and 58-67, drawn to a **peptide mimotope of P7 of SEQ ID NO: 7**.
22. Claims 42-43, 50, 53-54 and 58-67, drawn to a **peptide mimotope of P1 which is P15q of SEQ ID NO: 11**.
23. Claims 42-43, 50, 53-54 and 58-67, drawn to a **peptide mimotope of P1 which is PT1079 of SEQ ID NO: 13**.
24. Claims 42-43, 50, 53-54 and 58-67, drawn to a **peptide mimotope of P1 which is PT1079GS of SEQ ID NO: 15**.
25. Claims 42-43, 50, 53-54 and 58-67, drawn to a **peptide mimotope of P1 which is PT1078 of SEQ ID NO: 16**.
26. Claims 42-43, 50, 53-54 and 58-67, drawn to a **peptide mimotope of P1 which is PT15 of SEQ ID NO: 8**.

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27. Claims 42, 44, 50, 56 and 58-67, drawn to a **peptide mimotope** of P2 which is **P16 of SEQ ID NO: 24**, an immunogen comprising said peptide mimotope, a specific carrier and a vaccine comprising said peptide mimotope and adjuvant.
28. Claims 42, 45, 50, 57 and 58-67, drawn to a **peptide mimotope** of P2 which is **P17 of SEQ ID NO: 26**, an immunogen comprising said peptide mimotope, a specific carrier and a vaccine comprising said peptide mimotope and adjuvant.
29. Claims 68-72, drawn to a ligand (antibody) which is capable recognizing a surface exposed epitope of the Cε2 domain of IgE that is **not PTmAb0005**, a pharmaceutical composition comprising said ligand.
30. Claims 70-72, drawn to a pharmaceutical composition comprising a ligand wherein the ligand is **a monoclonal antibody PTmAb0005**.
31. Claim 73-74, drawn to a **peptide recognized by monoclonal antibody of PTmAb0005** and an immunogen comprising said peptide.
32. Claim 73-74, drawn to a **peptide recognized by monoclonal antibody of PTmAb0011** and an immunogen comprising said peptide.
33. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is **P1 of SEQ ID NO: 1**.
34. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is **P2 of SEQ ID NO: 2**.
35. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is **P3 of SEQ ID NO: 3**.
36. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is **P4 of SEQ ID NO: 4**.
37. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is **P5 of SEQ ID NO: 5**.

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38. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is P6 of **SEQ ID NO: 6**.
39. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a peptide comprising an isolated surface exposed epitope of the Cε2 domain of IgE and wherein the surface exposed epitope Cε2 is P7 of **SEQ ID NO: 7**.
40. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P1 of SEQ ID NO: 1**.
41. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P2 of SEQ ID NO: 2**.
42. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P3 of SEQ ID NO: 3**.
43. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P4 of SEQ ID NO: 4**.
44. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P5 of SEQ ID NO: 5**.
45. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P6 of SEQ ID NO: 6**.
46. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **non-peptide mimotope of P7 of SEQ ID NO: 7**.
47. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 1**.
48. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 2**.
49. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 3**.
50. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 4**.
51. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 5**.
52. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 6**.

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53. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 of SEQ ID NO: 7**.
54. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 which is P15q of SEQ ID NO: 11**.
55. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 which is PT1079 of SEQ ID NO: 13**.
56. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 which is PT1079GS of SEQ ID NO: 15**.
57. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 which is PT1078 of SEQ ID NO: 16**.
58. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P1 which is PT15 of SEQ ID NO: 8**.
59. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P2 which is P16 of SEQ ID NO: 24**.
60. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide mimotope of P2 which is P17 of SEQ ID NO: 26**.
61. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a ligand (antibody) which is capable recognizing a surface exposed epitope of the Cε2 domain of IgE that is **not PtMAb0005**.
62. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a ligand wherein the ligand is **a monoclonal antibody PTmAb0005**.
63. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide recognized by monoclonal antibody of PTmAb0005**.
64. Claims 75-76, drawn to a method of manufacturing a vaccine comprising a **peptide recognized by monoclonal antibody of PTmAb0011**.
65. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P1 of SEQ ID NO: 1**.
66. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P2 of SEQ ID NO: 2**.
67. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P3 of SEQ ID NO: 3**.

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68. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P4 of SEQ ID NO: 4**.
69. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P5 of SEQ ID NO: 5**.
70. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P6 of SEQ ID NO: 6**.
71. Claims 77-83, drawn to a method for treating allergy comprising administering a peptide to the patient wherein the surface exposed epitope Cε2 is **P7 of SEQ ID NO: 7**.
72. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 1** to the patient.
73. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 2** to the patient.
74. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 3** to the patient.
75. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 4** to the patient.
76. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 5** to the patient.
77. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 6** to the patient.
78. Claims 77-83, drawn to a method for treating allergy comprising administering a **non-peptide mimotope of P1 of SEQ ID NO: 7** to the patient.
79. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P1 of SEQ ID NO: 1** to the patient.
80. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P2 of SEQ ID NO: 2** to the patient.
81. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P3 of SEQ ID NO: 3** to the patient.
82. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P4 of SEQ ID NO: 4** to the patient.
83. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P5 of SEQ ID NO: 5** to the patient.

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84. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P6 of SEQ ID NO: 6** to the patient.
85. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P7 of SEQ ID NO: 7** to the patient.
86. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P1 which is P15q of SEQ ID NO: 11** to the patient.
87. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P1 which is PT1079 of SEQ ID NO: 13** to the patient.
88. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P1 which is PT1079GS of SEQ ID NO: 15** to the patient.
89. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P1 which is PT1078 of SEQ ID NO: 16** to the patient.
90. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P1 which is PT15 of SEQ ID NO: 8** to the patient.
91. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P2 which is P16 of SEQ ID NO: 24** to the patient.
92. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide mimotope of P2 which is P17 of SEQ ID NO: 26** to the patient.
93. Claims 77-83, drawn to a method for treating allergy comprising administering a ligand (antibody) which is capable recognizing a surface exposed epitope of the Cε2 domain of IgE that is **not PtMAb0005** to the patient.
94. Claims 77-83, drawn to a method for treating allergy comprising administering a ligand wherein the ligand is a **monoclonal antibody PTmAb0005** to the patient.
95. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide recognized by monoclonal antibody of PTmAb0005** to the patient.
96. Claims 77-83, drawn to a method for treating allergy comprising administering a **peptide recognized by monoclonal antibody of PTmAb0011** to the patient.

The inventions listed as Groups 1-96 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The WO 95/26365 publication (Oct 1995; PTO 892) teaches a peptide such as a human IgE of SEQ ID NO: 2 (See Table 2, in particular) and synthetic peptide thereof such as CH2/CH3 domains 207-218 (P2) for treating allergy (See entire document, abstract, page 6, in particular). The term "comprising" is open-ended. It expands the claimed peptide to include additional amino acids at either or both ends to read on the reference IgE. The surface exposed epitope is an inherent property of the reference peptide that contains the Cε2 domain as shown in page 6, and Table 2.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

5. Accordingly, Groups 1-96 are not so linked as to form a single general inventive concept and restriction is proper.
4. Due to the complexity of the claimed invention an oral restriction was not made.
5. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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8. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

August 25, 2003



CHRISTINA CHAN

SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 1600